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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,323	03/05/2002	Manfred Schmitt	100564-00082	5188

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EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/926,323	Applicant(s) SCHMITT ET AL.	
	Examiner Larry R. Helms	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-39 is/are pending in the application.
- 4a) Of the above claim(s) 36-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 30, 33, 34 have been amended.
2. Claims 36-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Election was made **without** traverse in Paper filed 5/10/04.
3. Claims 30-35 are under examination.
4. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.
5. The following Office Action contains NEW GROUNDS of Rejections.

Claim Objections

6. Claim 34 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim recites "or an antibody or antibody fragment having a binding specificity to the epitope 52-60 of uPAR". This phrase does not further limit claim 1 because claim 1 requires the antibody or antigen binding fragment to already bind residues 52-60 of uPAR.

Rejections Withdrawn

7. The rejection of claims 33-35 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention is withdrawn in view of the amendments to the claims.

8. The rejection of claims 30-33 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendments to the claims.

9. The rejection of claims 30-33 under 35 U.S.C. 112, first paragraph, is withdrawn in view of the amendments to the claims.

Response to Arguments

10. The rejection of claims 34-35 under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from the written description is maintained.

The response filed 10/14/04 has been carefully considered but is deemed not to be persuasive. The response states that the complete CDR sequences of the variable domains of IIIF10 are recited in the specification and in view of the disclosure one skill in the art could easily produce the antibody (see page 6 of response). In response to this argument, while the CDRs of the variable domains may be disclosed the claims require the entire antibody not just the CDRs such as the hinge, CH2, CH3 and as such

the entire antibody sequence must be disclosed, which is not, or a deposit is required. As no deposit is provided the rejection is maintained.

11. The rejection of claims 34-35 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. This is a written description rejection.

The response filed 10/14/04 has been carefully considered but is deemed not to be persuasive. The response states that the claims have been amended to recite that the antibody or antigen binding fragment binds the epitope of 52-60 of human uPAR (see page 6 of response). In response to this argument, claim 34 has been amended to recite "binding specificity to the epitope 52-60 of uPAR" and the claim depends on claim 34. Although the claim depends on claim 34 because of the 112 second issues (see below) it is unclear if the uPAR is the human uPAR or some other uPAR. As such the written description rejection is maintained.

12. The rejection of claim 35 under 35 U.S.C. 112, first paragraph, is maintained.

The response filed 10/14/04 has been carefully considered but is deemed not to be persuasive. The response states The claim depends from claim 34 and as such the antibody in claim 35 would have the binding specificity equivalent to IIIF10 and in addition have the recited sequences and one skilled in the art could easily produce the sequences shown in claim 35 and test the binding specificity (see pages 6-7 of response). In response to this argument, it is undue experimentation to only have

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disclosed two CDRs of an antibody and have to determine what other four CDRs would or could be combined with the disclosed two CDRs to obtain an antibody that would have the desired binding specificity. As evidenced from Rudikoff et al cited in the previous Office Action it is unpredictable whether one can alter the CDRs in an antibody and retain the required binding. In fact the art of Rudikoff et al demonstrates that even a single amino acid alteration in a CDR can obliterate the binding. The claim only describes two of the CDR sequences and encompasses a myriad of sequences for the other four CDRs and in view of the lack of Guidance in the specification and the lack of predictability in the art, one of skill in the art would be required to perform undue experimentation in order to practice the claimed invention.

13. The rejection of claims 30-35 under 35 U.S.C. 103(a) as being unpatentable over Dano et al (US Patent 5,519,120, issued 5/96) and further in view of Luther et al (American Journal of Pathology 150:1231-1244, 1997, IDS 10/15/01) and Heiss et al (Nature Medicine 1:1035-1039, 1995, IDS 10/15/01) and Terstappen (US Patent 5,234,816, issued 8/93, IDS 10/15/01) is maintained.

The response filed 10/14/04 has been carefully considered but is deemed not to be persuasive. The response seems to argue that none of the references teach an antibody that binds to 52-60 of uPAR (Dano, Heiss, and Terstapen) or that Luther does not indicate that the IIIF10 antibody can discriminate the epitope of 52-60 of uPAR from a normal cell and the same epitope from a tumor cell (see page 7 of the response). In response to this argument, it appears that the response is arguing the references

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separately when the rejection is a combination of references and in response to this, one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In addition, it is unclear what the argument that Luther does not indicate that the IIIF10 antibody does not discriminate cancer cells from normal has to do with the rejection in view that claims 34 and 35 actually recites the IIIF10 antibody. Are applicants stating on the record that the IIIF10 antibody can not be used in the invention and are claiming something that does not work or have utility? Irregardless of whether Luther does not disclose a discrimination, the claims do not require discrimination between tumor and normal all the claims require is a cancer sample and testing for antigen binding by using the IIIF10 antibody, which as indicated in the specification on page 9 "it was found that the binding of the antibody IIIF10 or of a corresponding antibody with the equivalent binding capability has a significant prognostic relevance" can be used in the invention. There is no indication that the IIIF10 antibody of Luther can not be used in the invention or is different from that claimed in claim 34 and 35. As such the IIIF10 antibody of Luther is the same as that claimed and has the identical properties and can be used in the invention. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical

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structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

The following is a NEW GROUND of Rejection

14. Claims 34-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 34 is indefinite for reciting "specificity of the epitope 52-60 of uPAR".

Although the claim depends on claim 30, it is unclear whether the antibody binds the human uPAR or some other uPAR from some other source. As such the claim is indefinite

Conclusion

15. No claim is allowed.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew, can be reached on (571) 272-0787.

18. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is ~~(703) 308-4242~~.

571 272 8300

Respectfully,

Larry R. Helms Ph.D.

571-272-0832



LARRY R. HELMS, PH.D
PRIMARY EXAMINER